Food Safety: Risk - Benefit Assessment

John Gilbert
Food and Environment Research Agency York (UK)
Outline of talk

1. Introduction
   Risk assessment
   Benefit assessment
2. Examples in food safety area
3. EU projects
   QALIBRA - FP6 project
   BRAFO - SSA project
4. EFSA Scientific Colloquium - July 2006
5. Conclusions
Scientific developments

- Analytical techniques have continued to improve with ever-increasing capability to find smaller and smaller amounts
- Exposure assessment developing and more refined (probabilistic modeling)
- Toxicological assessment getting left behind
- Benefit assessment - very new science, tools only recently being developed
Some examples of risk-benefit

- Fish consumption - dioxins vs PUFAs, Hg vs PUFAs & Se
- Nitrate from leafy vegetables
- Sulfiting agents - adverse effects vs antimicrobial benefits
- Food supplements and nutrient sources
- Packaging - azodicarbonamide blowing agent
Benefits of fish consumption (n-3 PUFA)

- Fish consumption has a beneficial effect on cardio-vascular disease and mortality.

- Increased fish intake by 1 serving/week might reduce coronary mortality by 4%/annum in Norway (Konig, 2005).

- Beneficial health effects for the foetus and the child - increased birth wt; positive effects on visual ability; positive neuropsychological development.

- Vitamins A, D, B12, iodine and selenium intake from fish.
Dose-response relationship for fish consumption and CHD

Is there a dose-response relationship?

Regression of CHD mortality risk versus fish consumption in the general population.

The area of each data point is proportional to its statistical weight.

CHD, coronary heart disease.

Ref: Konig et al 2005
Risks from fish consumption

• Exposure to dioxins and PCBs - particularly from oily fish
  Higher levels from contaminated waters and some species

• Exposure to mercury
  Large variations in concentration between species
  Shark, blue marlin and swordfish - high levels
Mercury and selenium content in flesh of local fish

Ref: Dewailly et al. 2008 FAC Vol 25 1334
Risk-benefit of green vegetable consumption - EFSA Opinion

• **Benefit**
  • Increased consumption of vegetables recommended as beneficial
  • (5 portions a day)
  • Impacts on cancer, obesity, diabetes, cardiovascular disease

• **Risk**
  • Acceptable daily intake of nitrate = 3.7 mg/kg b.w./day
  • Equivalent to 222 mg nitrate per day for 60 kg adult
  • Average consumption of mixed vegetables (9400g) contributes 157 mg nitrate/day

Source:- EFSA Journal (2008) 689, 1-79
Nitrate levels in lettuce
(EFSA Journal 2008 689:1-79)

Levels of nitrate in lettuce varieties as influenced by season, production system and region. Thick bars illustrate the number of sample results (left y-axes) and thin bars the 5th, 50th (crossbar) and 95th percentile values in mg/kg (right y-axes).
Levels of nitrate in rucola as influenced by season, production system and region. Thick bars illustrate the number of sample results (left y-axes) and thin bars the 5th, 50th (crossbar) and 95th percentile values in mg/kg (right y-axes).
Food supplements and nutrient sources

• Micronutrients:-
  e.g. selenium, calcium, magnesium, chromium, cobalt, copper, silicon, etc

• Sources:-
  e.g. metal salts or complexes or incorporated into biological materials (enriched yeasts)

• Need to assess the source used to deliver the nutrient
The traditional approach to setting an upper level

Need to ensure that setting the upper intake level does not produce deficiency.
Packaging - azodicarbonamide blowing agent

Issue (risk):-

• Azodicarbonamide used in plasticol seals in metal jar caps can degrade to semicarbazide (SEM)

• SEM found in range 0-3.3 ng/g in baby food

• Maximum SEM exposure = 0.5 - 0.66 µg/kg/bw day for infant <1 year

• >21000 margin of safety (Nestmann, 2005)
Benefits of baby food jar closure technology

- Benefits of commercial baby food - safe, convenient, nutritionally balance food source
- Hemetic seal provides long shelf-life for pasteurized or sterilized foods
- Seal integrity provides security
Lessons to be learnt from examples:-

• Risks easier to assess than benefits - risks health-related

• Risks may be multi-faceted - multiple exposure

• Benefits may be health related

• Benefits may also be technological

• Need common currency to compare risk and benefit
WHO Global Burden of Disease (GBD) project

• Disability-Adjusted Life Year (DALY) – as a single measure to quantify the burden of diseases, injuries and risk factors.

• DALY is based on years of life lost from premature death and years of life lived in less than full health.

• Updated for the year 2000-2002 and included a more extensive analysis of the mortality and burden of disease attributable to 26 global risk factors using a consistent analytical framework known as Comparative Risk Factor Assessment (CRA).

http://www.who.int/healthinfo/global_burden_disease/about/en/index.html
QALIBRA

http://www.qalibra.eu/

- QALIBRA is an FP6 project co-ordinated by Matis of Iceland. Duration April 2006 - Sept. 2009.

- To assess the balance between the risks and benefits associated with a particular food, they must be converted into a common measure of net health impact.

- QALIBRA has developed methods that can take account of multiple risks, benefits and uncertainties and implement them in web-based software for assessing net health impacts.
QALIBRA Tool

QALIBRA aims to develop methods for quantitative risk-benefit analysis of foods to handle:-

- multiple risks
- benefits
- uncertainties

Available to stakeholders as web-enabled software – the QALIBRA tool.
Application of the QALIBRA tool

The analysis includes the following steps:

- Define two alternative Dietary Scenarios for which Health Effects are to be assessed, and the population they relate to
- Identify hazardous and beneficial compounds in each diet and their corresponding Health Effects
- Use Dose-Response relationships to simulate which members of the population experience the Health Effects in each Dietary Scenario
- Find the sum of the Health Effects in terms of a Common Currency for each Dietary Scenario
- Calculate the Net Health Impact for the change in Dietary Scenario
QALIBRA tool in schematic form

Setup | Scenarios

Intakes and Health Effects

- Exposure Constituent 1
- Dose-Response Function 1
- Health Endpoint 1

Valuation

- Select Common Currency
- Valuation
- Health Impact 1

Calculate

Population & Dietary Scenarios

Health Effects

- Exposure Constituent 2
- Dose-Response Function 2
- Health Endpoint 2

More Health Effects
BRAFO project

http://www.brafo.org/brafo

BRAFO is an EU Specific Support Action project to Investigate the Risk Benefit Analysis for Foods co-ordinated by ILSI Europe.

Duration:- Sept 2007- December 2010

Risk benefit analyses for the following food groups:
• fish and soy (natural foods);
• folic acid and macronutrient replacers (dietary interventions);
• heat processed compounds.
Interactions between QUALIBRA and Brafo

- RIVM and CSL participate in Brafo WP3
- Exchange of information
- Potential for Brafo to use & evaluate Qalibra software
- Proposed steps:
  Share information about Brafo case studies
  Qalibra assess feasibility of adapting the software
  If successful: Brafo case study WPs invited to evaluate software and participate in Qalibra final workshop, Budapest, w/b 8 June 2009
Format of Scientific Colloquium

102 participants (including 21 EFSA staff)

Five presentations

Discussion Groups;

- Nutrient content vs toxic contaminants/constituents
- Food fortification and functional foods
- Food preservation vs. microbial hazards
Conclusions

• Historically in food safety too much focus on 'risk' without considering 'benefit'

• Many real examples where considering 'benefit' brings balance to the assessment process

• Need for common currency to undertake risk/benefit (DALY)

• EU projects and EFSA beginning to tackle very difficult area